

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN; the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK; *ex rel.*, STEVEN M. CAMBURN  
Plaintiffs and Relator,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,  
Defendant.

**No. 13 Civ. 3700 (KMW)**

**STIPULATED  
CONFIDENTIALITY  
AGREEMENT AND  
PROTECTIVE ORDER**

THE HONORABLE GABRIEL W. GORENSTEIN, UNITED STATES MAGISTRATE JUDGE:

WHEREAS, all of the parties to this action (collectively, the “Parties” and each individually, a “Party”) request that this Court issue a protective order pursuant to Federal Rule of Civil Procedure 26(c) to protect the confidentiality of nonpublic and competitively sensitive information that they may need to disclose in connection with discovery in this action or that they may otherwise produce or disclose to the opposing Party;

WHEREAS, the Parties, through their counsel, as evidenced by their signatures below, agree to the following terms; and

WHEREAS, this Court finds that good cause exists for issuance of an appropriately tailored confidentiality order governing the pretrial phase of this action;

IT IS HEREBY ORDERED that the Parties to this action, their respective officers, agents, servants, employees, and attorneys, any other person in active concert or participation with any of the foregoing, and all other persons with actual notice of this Order will adhere to the following terms, upon pain of contempt:

1. With respect to “Discovery Material” (*i.e.*, information of any kind produced or disclosed in the course of discovery or otherwise in this action) that a person has designated as “Confidential” pursuant to this Order, no person subject to this Order may disclose such Confidential Discovery Material to anyone else except as expressly permitted hereunder:

2. The Party or person producing or disclosing Discovery Material (each, “Producing Party”) may designate as Confidential only the portion of such material that it reasonably and in good faith believes consists of:

- (a) previously non-disclosed<sup>1</sup> financial information (including without limitation profitability reports or estimates, percentage fees, design fees, royalty rates, minimum guarantee payments, sales reports, and sale margins);
- (b) previously non-disclosed material relating to ownership or control of any non-public company;
- (c) previously non-disclosed business plans, product-development information, or marketing plans;

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<sup>1</sup> For purposes of this protective order, previously non-disclosed information includes information disclosed under seal or pursuant to a protective order.

- (d) previously non-disclosed information related to formulas, patterns, programs, plans, devices, methods, techniques, or processes used for the preparing, manufacturing, or processing of pharmaceutical or biological products;
- (e) any information protected from disclosure by applicable trade secrets law, including the Uniform Trade Secrets Act (adapted by the vast majority of states) and the Defend Trade Secrets Act (18 U.S.C. § 1839);
- (f) health care information subject to protection under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), Privacy Rule, 45 C.F.R. §§ 160 and 164, and/or other applicable state or federal law concerning confidential health information;
- (g) personal data subject to protection under the General Data Protection Regulation (GDPR) and/or other applicable foreign national data protection laws;
- (h) a trade secret or other confidential research, development or information;
- (i) any information of a personal or intimate nature regarding any individual; or
- (j) any other category of information given confidential status by this Court after the date of this Order.

Information to be treated as “Confidential” under this order includes all materials labeled as confidential that have been produced to the United States Attorney’s Office for the Southern District of New York in response to any Civil Investigative Demand or subpoenas in connection with the investigation related to this action.

3. With respect to the Confidential portion of any Discovery Material other than deposition transcripts and exhibits, the Producing Party or its counsel may designate such portion as “Confidential” by: (a) stamping or otherwise clearly marking as “Confidential” the protected portion in a manner that will not interfere with legibility or audibility; and (b) producing for future public use another copy of said Discovery Material with the confidential information redacted.

4. A Producing Party or its counsel may designate deposition exhibits or portions of deposition transcripts as Confidential Discovery Material either by: (a) indicating on the record during the deposition that a question calls for Confidential information, in which case the reporter will bind the transcript of the designated testimony in a separate volume and mark it as “Confidential Information Governed by Protective Order;” or (b) notifying the reporter and all counsel of record, in writing, within 30 days after a deposition has concluded, of the specific pages and lines of the transcript that are to be designated “Confidential,” in which case all counsel receiving the transcript will be responsible for marking the copies of the designated transcript in their possession or under their control as directed by the Producing Party or that person’s counsel. During the 30-day period following a deposition, all Parties will treat the entire deposition transcript as if it had been designated Confidential.

5. If at any time before the termination of this action a Producing Party realizes that it should have designated as Confidential some portion(s) of Discovery Material that it previously produced without limitation, the Producing Party may so designate such material by notifying all Parties in writing. Thereafter, all persons subject to this Order will treat such designated portion(s) of the Discovery Material as Confidential.

6. Nothing contained in this Order will be construed as: (a) a waiver by a Party or person of its right to object to any discovery request; (b) a waiver of any privilege or protection; or (c) a ruling regarding the admissibility at trial of any document, testimony, or other evidence.

7. Where a Producing Party has designated Discovery Material as Confidential, other persons subject to this Order may disclose such information only to the following persons:

- (a) the Parties to this action, their insurers and their external auditors;
- (b) counsel retained specifically for this action, including any paralegal, clerical, or other assistant that such outside counsel employs and assigns to this matter;
- (c) outside vendors or service providers (such as copy-service providers and document-management consultants) that counsel hire and assign to this matter;
- (d) any mediator or arbitrator that the Parties engage in this matter or that this Court appoints, provided such person has first executed a Non-Disclosure Agreement in the form annexed as Exhibit A hereto;
- (e) as to any document, its author, its addressee, and any other person indicated on the face of the document as having received a copy;
- (f) any witness who counsel for a Party in good faith believes may be called to testify at trial or deposition in this action, provided such person does not retain any copies of Discovery Material designated as “Confidential” and

has first executed a Non-Disclosure Agreement in the form annexed as Exhibit A hereto;

- (g) any person a Party retains to serve as an expert witness or otherwise provide specialized advice to counsel in connection with this action, provided such person has first executed a Non-Disclosure Agreement in the form annexed as Exhibit A hereto;
- (h) stenographers engaged to transcribe depositions the Parties conduct in this action; and
- (i) this Court, including any appellate court, its support personnel, and court reporters.

8. Before disclosing any Confidential Discovery Material to any person referred to in subparagraphs 7(d), 7(f), or 7(g) above, counsel must provide a copy of this Order to such person, who must sign a Non-Disclosure Agreement in the form annexed as Exhibit A hereto stating that he or she has read this Order and agrees to be bound by its terms. Said counsel must retain each signed Non-Disclosure Agreement, hold it in escrow, and produce it to opposing counsel either before such person is permitted to testify (at deposition or trial) or at the conclusion of the case, whichever comes first.

9. This Order binds the Parties and certain others to treat as Confidential any Discovery Materials so classified. The Court has not, however, made any finding regarding the confidentiality of any Discovery Materials, and retains full discretion to determine whether to afford confidential treatment to any Discovery Material designated as Confidential hereunder. All persons are placed on notice that the Court is unlikely to seal or otherwise afford confidential

treatment to any Discovery Material introduced into evidence at trial, even if such material has previously been sealed or designated as Confidential.

10. The Parties shall fully comply with Rule 5 of Judge Wood's Individual Rules of Practice regarding the electronic filing under seal in civil/miscellaneous cases. Motions or Letter Motions for approval of sealed or redacted filings, including the proposed sealed document(s), must be filed electronically through the court's ECF system in conformity with the Court's standing order, 19-mc-00583, and ECF Rules & Instructions, Section 6. The motion must be filed in public view, must explain the particular reasons for seeking to file that information under seal and should not include confidential information sought to be filed under seal. Supporting papers must be separately filed electronically and may be filed under seal or redacted only to the extent necessary to safeguard information sought to be filed under seal. The proposed sealed document must be contemporaneously filed under seal in the ECF system and electronically related to the motion. Where the motion seeks approval to redact information from a document that is to be publicly filed, the filing party shall: (a) publicly file the document with the proposed redactions, and (b) electronically file under seal a copy of the unredacted document with the redactions highlighted. Both documents must be electronically filed through the ECF system and related to the motion.

11. To be approved, any redaction or sealing of a court filing must be narrowly tailored to serve whatever purpose justifies the redaction or sealing and must be otherwise consistent with the presumption in favor of public access to judicial documents. *See, e.g., Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 119-20 (2d Cir. 2006). In general, the parties' consent or the fact that information is subject to a confidentiality agreement between litigants is not, by itself, a valid basis to overcome the presumption in favor of public access to

judicial documents. *See, e.g., In re Gen. Motors LLC Ignition Switch Litig.*, No. 14-MD-2543(JMF), 2015 WL 4750774, at \*4 (S.D.N.Y. Aug. 11, 2015). The party seeking leave to file sealed or redacted materials should meet and confer with any opposing parties (or third parties seeking confidential treatment of the information, if any) in advance to narrow the scope of the request. When a party seeks leave to file sealed or redacted materials on the ground that an opposing party or third party has requested it, that party shall notify the opposing party or third party that it must file, within three days, a letter explaining the need to seal or redact the materials. Any party unable to comply with the requirement for electronic filing under seal through the ECF system, or who has reason to believe that a particular document should not be electronically filed, must move for leave of the Court to file in the traditional manner, on paper.

12. In filing Confidential Discovery Material with this Court, or filing portions of any pleadings, motions, or other papers that disclose such Confidential Discovery Material (“Confidential Court Submission”), to the extent that they are permitted to file any such materials under seal, the Parties shall publicly file a redacted copy of the Confidential Court Submission via the Electronic Case Filing System. The Parties shall also file an unredacted copy of the Confidential Court Submission under seal with the Clerk of this Court, and the Parties shall serve this Court and opposing counsel with unredacted courtesy copies of the Confidential Court Submission.

13. Any Party who objects to any designation of confidentiality may at any time before the trial of this action serve upon counsel for the Producing Party a written notice stating with particularity the grounds of the objection. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 2.B of Judge Gorenstein's Individual Practices.

14. Any Party who requests additional limits on disclosure (such as “attorneys’ eyes only” in extraordinary circumstances), may at any time before the trial of this action serve upon counsel for the recipient Parties a written notice stating with particularity the grounds of the request. If the Parties cannot reach agreement promptly, counsel for all affected Parties will address their dispute to this Court in accordance with paragraph 2.B of Judge Gorenstein's Court's Individual Rules of Practice in Civil Cases.

15. Recipients of Confidential Discovery Material under this Order may use such material solely for the prosecution and defense of this action and any appeals thereto, and not for any other purpose or in any other litigation proceeding. Nothing contained in this Order, however, will affect or restrict the rights of any Party with respect to its own documents or information produced in this action.

16. Nothing in this Order will prevent any Party from producing any Confidential Discovery Material in its possession in response to a lawful subpoena or other compulsory process, or if required to produce by law or by any government agency having jurisdiction, provided that such Party gives written notice to the Producing Party as soon as reasonably possible, and if permitted by the time allowed under the request, at least 10 days before any disclosure. Upon receiving such notice, the Producing Party will bear the burden to oppose compliance with the subpoena, other compulsory process, or other legal notice if the Producing Party deems it appropriate to do so.

17. Each person who has access to Discovery Material designated as Confidential pursuant to this Order must take all due precautions to prevent the unauthorized or inadvertent disclosure of such material.

18. In the event of a disclosure of any Confidential Discovery Material to a person not authorized to have had such disclosure made to him or her under this Order, and in the event the party responsible for having made or allowed such disclosure becomes aware of such disclosure, that party shall immediately inform counsel for the Producing Party whose Confidential Discovery Material has thus been disclosed of all relevant information concerning the nature and circumstances of such disclosure. The responsible party also shall take all reasonable measures promptly to retrieve the Confidential Discovery Material and to ensure that there is no further or greater unauthorized disclosure of the Confidential Discovery Material.

19. If a Producing Party believes that it has, for any reason, inadvertently disclosed documents, testimony, information and/or things protected from disclosure under the attorney-client privilege, work-product protection or any other legal privilege or immunity protecting such information from discovery, or the Receiving Party discovers such disclosure, the disclosure, pursuant to Fed. R. Evid. 502(d) shall not be deemed a waiver—in this litigation or in any other proceeding, including in Federal, State, arbitral, foreign, or other proceedings—of the applicable privilege or protection.

Upon such discovery, by either the Producing Party or the Receiving Party, prompt written notice identifying such materials shall be provided to the non-discovering party. The Receiving Party shall immediately return to the Producing Party, or destroy, all summaries or copies of such documents, testimony, information and/or things, shall provide a certification of counsel that all such disclosed materials (including copies or summaries of such material) have been returned or completely destroyed and shall not use such items for any purpose until further order of the Court.

In all events, such return or destruction and certification must occur within five (5) business days of the receipt of the request. Within fifteen (15) business days of the notification that the disclosed materials have been returned or destroyed, the Producing Party shall produce a privilege log with respect to the disclosed materials. Alleged privileged documents shall remain protected against disclosure and use during the pendency of any dispute over their status. Nothing in this Stipulation and Order shall affect any Party's right to withhold from disclosure documents or information that are privileged or otherwise protected from disclosure.

20. Within 60 days of the final disposition of this action—including all appeals—all recipients of Confidential Discovery Material must either return it—including all copies thereof—to the Producing Party, or, upon permission of the Producing Party, destroy such material—including all copies thereof. In either event, by the 60-day deadline, the recipient must certify its return or destruction by submitting a written certification to the Producing Party that affirms that it has not retained any copies, abstracts, compilations, summaries, or other forms of reproducing or capturing any of the Confidential Discovery Material. Notwithstanding this provision, the attorneys that the Parties have specifically retained for this action may retain an archival copy of all pleadings, motion papers, transcripts, expert reports, legal memoranda, correspondence, or attorney work product, even if such materials contain Confidential Discovery Material. Any such archival copies that contain or constitute Confidential Discovery Material remain subject to this Order. This paragraph does not apply to the Court.

21. This Order will survive the termination of the litigation and will continue to be binding upon all persons subject to this Order to whom Confidential Discovery Material is produced or disclosed.

22. This Court will retain jurisdiction over all persons subject to this Order to the extent necessary to enforce any obligations arising hereunder or to impose sanctions for any contempt thereof.

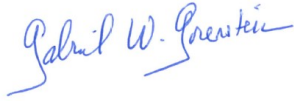
RESPECTFULLY SUBMITTED, SO STIPULATED AND AGREED.

Dated: September 24, 2020

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| <p>SHEPHERD, FINKELMAN,<br/>MILLER &amp; SHAH, LLP</p> <p><u>/s/ Laurie Rubinow</u><br/>James E. Miller<br/>Laurie Rubinow (LR6637)<br/>65 Main Street<br/>Chester, CT 06412<br/>Tel: (860) 526-1100<br/>Fax: (866) 300-7367<br/>Email: <a href="mailto:lrubinow@sfmslaw.com">lrubinow@sfmslaw.com</a><br/><a href="mailto:jmiller@sfmslaw.com">jmiller@sfmslaw.com</a></p> <p><i>Attorneys for Plaintiff-Relator</i></p> | <p>CRAVATH, SWAINE<br/>&amp; MOORE LLP</p> <p><u>/s/ Benjamin Gruenstein</u><br/>Evan R. Chesler<br/>Benjamin Gruenstein<br/>Damaris Hernandez<br/>Worldwide Plaza<br/>825 Eighth Avenue<br/>New York, NY 10019<br/>Tel: (212) 474-1000<br/>Email: <a href="mailto:echesler@cravath.com">echesler@cravath.com</a><br/><a href="mailto:bgruenstein@cravath.com">bgruenstein@cravath.com</a><br/><a href="mailto:dhernandez@cravath.com">dhernandez@cravath.com</a></p> <p><i>Attorneys for Defendant</i></p> |
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IT IS SO ORDERED.

Dated: September 24, 2020  
New York, New York

  
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Gabriel W. Gorenstein  
United States Magistrate Judge

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN; the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK; *ex rel.*, STEVEN M. CAMBURN  
Plaintiffs and Relator,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,  
Defendant.

**No. 13 Civ. 3700 (KMW)**

**NON-DISCLOSURE  
AGREEMENT**

I, \_\_\_\_\_, acknowledge that I have read and understand the Protective Order in this action governing the non-disclosure of those portions of Discovery Material that have been designated as Confidential. I agree that I will not disclose such Confidential Discovery Material to anyone other than for purposes of this litigation and that at the conclusion of the litigation I will return all discovery information to the Party or attorney from whom I received it. By acknowledging these obligations under the Protective Order, I understand that I am submitting myself to the jurisdiction of the United States District Court for the Southern District of New York for the purpose of any issue or dispute arising hereunder and that my willful violation of any term of the Protective Order could subject me to punishment for contempt of Court.

\_\_\_\_\_  
Name:

Date: